

## REMARKS

The Office action dated May 28, 2003 is acknowledged. Claims 13-28 are pending in the instant application and have been rejected by the present Office action. By the present response, claims 13, 15, 18, 24 and 26-28 have been amended. In addition, claim 14 has been deleted with the pertinent material having been incorporated into independent claim 13. Reconsideration is respectfully requested in light of the amendments being made hereby and of the following remarks.

### Claim Objections

The Examiner has objected to claims 14 and 19 because of various informalities. Applicant submits that claim 14 has been deleted and claim 19 has been corrected according to the Examiner's suggestion provided at paragraph 3 in the Office action dated May 28, 2003. Accordingly, it is requested that this objection be withdrawn.

### Rejection of Claims 13-28 under 35 U.S.C. 112, second paragraph

Claims 13-28 have been rejected under 35 U.S.C., second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 13, the Examiner states that the phrase "placing the adhesive in a support position" is indefinite. Claim 13 has been amended according to the Examiner's suggestion.

Regarding claim 18, the Examiner states that the phrase "inscribing the laser-exposed information in the form of characters or signs onto the underlying layer to be inscribed"

appears to be indefinite and therefore misleading. Applicant has also adopted the Examiner's suggested amendment with regards to this claim.

Regarding claim 24 and 27, the Examiner states that the phrase "data generated by other production steps" is indefinite. Accordingly, both claims have been amended to delete the phrase "by other production steps" in order to remove any ambiguity.

Regarding claims 26 and 28, the Examiner states that the phrase "means for the control of the laser beam" is indefinite. Accordingly, both of these claims have also been amended to delete any supposed ambiguity by clearly providing what the "means for the control of the laser beam" is.

Because each of the above-referenced claims were amended to more clearly define what the applicant regards as the invention, it is respectfully requested that this rejection be withdrawn.

**Rejection of Claims 13-28 under 35 U.S.C. 103(a)**

Claims 13-28 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Applicant's Acknowledged Prior Art (AAPA) provided in the specification in view of WO 97/44196 (Clement et al.). Regarding claims 13-21 and 25, according to the Examiner, the AAPA teaches each of the features claimed in the present invention, except for the control of the intensity and penetration depth of the laser beam according to the material properties of the system in such a way that the laser beam does not penetrate far enough to reach one of the at least one ingredient-containing layers and preventing a detrimental influence on the ingredients contained in the system. In addition, the Examiner states that the AAPA fails to teach that the overlying layer is a color layer which disintegrates at a

moderate laser irradiation level, the overlying layer having a conspicuous color relative to the layer to be inscribed, applying at least two overlying pigmented layers to the layer to be inscribed, and further including disintegrating the at least two pigmented layers by accurate control of the penetration depth of the laser beam to visualize the at least two underlying pigmented color layers.

The Examiner relies on Clement et al. which, according to the Examiner, discloses a method for forming visible images by laser radiation with the energy as well as the depth or penetration of the laser beam being carefully programmed and/or adjusted such that only selective overlying layers are ablated at the depth of the selected layer without affecting further layers, the overlying layers being colored layers so as to selectively reveal different layers, the ablation of the specific layer including the uppermost overlying layer of the two top overlying layers.

It is the Examiner's opinion that it would have been obvious for one having ordinary skill in the art to have modified the device according to the AAPA with the aforementioned teachings of Clement et al. with the motivation to allow the laser beam to penetrate to a specific depth to expose the required pigment.

Regarding claims 22-24 and 26-28, the Examiner states in the present Office action that those claims are unpatentable over the AAPA, in view of Clement et al., and further in view of U.S. Patent No. 5,151,572 (Jack). The Examiner states that the AAPA in view of Clement et al. discloses every feature recited in these claims, except for the programmable central control unit including a keyboard and accepting transferred data. The Examiner relies on Jack which discloses a method and apparatus for making a stencil for etching glass using

a laser beam to cut through the thin stencil template from a label, the apparatus including a host computer with a user input device (keyboard) and a laser interface card such that the parameters of the laser beam are controlled based on a user interface control software stored in the host computer. The Examiner's opinion is that it would have been obvious for one skilled in the art to incorporate control software as taught by Jack in the AAPA device modified according to Clement et al. with the motivation to provide a consistent, repeatable process of inscribing information on the label with precision.

Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references when combined must teach or suggest all of the claim limitations (emphasis added). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure (M.P.E.P. Sec. 706.02(j)). It is the Applicant's contention that none of the references, alone or in combination, teaches each and every feature of the present invention as recited in the amended claims. Specifically, none of the references, even when considered in combination, disclose a toner-free process for inscription of a sheet-like active agent-containing therapeutic system. It is therefore respectfully requested that the application defined in the claims is patentably distinguishable over the referenced prior art under 35 U.S.C. 103(a). Based on these differences explained in more detail below, Applicant respectfully submits that each and every element of the present invention as defined in claims 13-28 is not set forth in any of the prior art references,

alone or in combination, and therefore would not be obvious by the same. Therefore, Applicant respectfully requests that this rejection be withdrawn.

Applicant turns first to the referenced AAPA provided in the present specification. It should be noted that the present application does not set forth or disclose the use of direct laser inscription for transdermal therapeutic systems. It is only disclosed that screen printing and tampon printing are printing techniques known to be employed for labeling active ingredient containing adhesive systems (page 2 of the specification, last paragraph). It is further disclosed that ink jet printers are known to be utilized for labeling such adhesive systems (page 3, 2<sup>nd</sup> paragraph). Finally, it is provided in the AAPA that an inscription by means of a movable guided laser beam utilizing toners are known to label active ingredient containing systems. Applicant submits that one skilled in the art would instantly understand that a xerographic process is one where the laser beam is directed towards an electrically charged photoconductive insulating surface in which the latent image is developed with a resinous powder (i.e. toner) and then transformed onto the surface to be labeled.

Applicant further submits that the AAPA additionally states that inscription techniques by means of a movable guided laser beam, wherein the laser beam is directed towards the substrate to be inscribed, is known for labeling light metal or comparatively thick layers of plastic or rubber (page 4, 1<sup>st</sup> paragraph). However, utilizing toner-free laser inscription on thin, sheet-like adhesive systems comprising active ingredients is not disclosed anywhere in the AAPA.

Applicant submits that Clement et al. teaches the production of visible images by laser radiation with energy and depth of penetration of the laser beam being adjusted such

that only selective overlying layers are ablated without affecting further layers underneath.

Applicant submits that Clement et al. further discloses at page 4, paragraph 3 that the thickness of the coat is limited by accuracy of the laser beam in penetrating to significant depth and that the thickness of various layers will influence that amount of energy which is required for ablation. It is apparent that Clement et al. does not provide any information or teaching beyond that which was provided in the AAPA. In addition, Clement et al. does not indicate that toner-free laser inscription, such as is recited in independent claim 13, as amended, may overcome the various disadvantages noted in the AAPA, namely that this technique is not precise enough to reliably avoid damage to other layers, such as in the case where active ingredient containing systems are being inscribed where the individual layers are exceptionally thin.

Applicant also respectfully points out that Clement et al. does not disclose any dimensions for a suitable thickness of the layers having different hues or reflection densitites. Therefore, it is the Applicant's belief that it would not be obvious to one having ordinary skill in the art to combine the teachings of the AAPA with Clement et al. in order to arrive at the present invention. Moreover, it is the Applicant's belief that such a combination does not teach each and every limitation recited in claims 13-28. Therefore, it is respectfully requested that this rejection be withdrawn.

Turning now to the rejection directed to claims 22-24 and 26-28 for the AAPA in view of Clement et al. and further in view of Jack, Applicant respectfully submits that this rejection should be withdrawn for at the following reasons. Claims 22-24 depend from claim 13, and therefore the subject invention as recited in claims 22-24 are not obvious over the

AAPA in view of Clement et al. and further in view of Jack for at least the aforementioned reasons noted in connection with claim 13. Furthermore, the addition of Jack fails to make up for the aforementioned deficiencies of the AAPA alone or in view of Clement et al. Specifically, Jack teaches cutting through a facestock and adjacent layers for making a stencil for etching glass (Fig. 5). The reference does not relate to, nor does it address, the disadvantages in the art that the present invention seeks to address in any of the claims, namely claims 22-24 and 26-28. Therefore, it is respectfully requested that this rejection also be withdrawn.

### Conclusion

For the foregoing reasons, it is believed that the present application as amended is in condition for allowance, and such action is earnestly solicited. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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